Biotech Daily

Monday February 4, 2013

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: BENITEC UP 7%, NEUREN DOWN 5%**

*** WEHI, SYNCHROTRON CAPTURE CELL DEATH**

*** ALCHEMIA COMPLETES PHASE III HA-IRINOTECAN RECRUITMENT**

*** BIONOMICS BNC375 ENHANCES RODENT EPISODIC, WORKING MEMORY**

*** CALZADA, POLYNOVO RECRUIT 20-PATIENT NOVOSORB WOUND TRIAL**

*** CIRCADIAN NEARS COMPLETION OF PHASE I VGX-100 TUMOR TRIAL**

*** GRAHAM EDWARDS, MONTOYA TAKE 5.5% OF PHARMAXIS**

MARKET REPORT

The Australian stock market fell 0.28 percent on Monday February 4, 2013 with the S&P ASX 200 down 13.6 points to 4,907.5 points.

Eight of the Biotech Daily Top 40 stocks were up, 15 fell, 13 traded unchanged and four were untraded. All three Big Caps fell.

Benitec was the best, up 0.1 cents or 7.1 percent to 1.5 cents with 875,500 shares traded.

Prima and Reva climbed more than four percent; Circadian and Sunshine Heart were up more than three percent; Mesoblast rose 2.7 percent; with Bionomics and Clinuvel up more than one percent.

Neuren led the falls, down 0.2 cents or 5.1 percent to 3.7 cents with 5.6 million shares traded.

Acrux, Allied Health and Avita fell more than four percent; both Starpharma and Viralytics were down 3.3 percent; QRX and Sirtex shed two percent or more; Compumedics, Genetic Technologies, Heartware, Tissue Therapies and Universal Biosensors were down more than one percent; with Cochlear, CSL, Nanosonics, Pharmaxis and Resmed down by less that one percent.

THE WALTER AND ELIZA HALL INSTITUTE FOR MEDICAL RESEARCH

The Walter and Eliza Hall Institute says its researchers have for the first time visualized the molecular changes in a critical cell death protein that force cells to die.

The Institute said the finding "provides important insights into how cell death occurs, and could lead to new classes of medicines that control whether diseased cells live or die".

WEHI said that cell death, or apoptosis, was important for controlling the number of cells in the body and defects in cell death were linked to the development of diseases such as cancer and neurodegenerative conditions.

The Institute said that insufficient cell death could cause cancer by allowing cells to become immortal while excessive cell death of neurons could be a cause of neurodegenerative conditions.

WEHI said that Dr Peter Czabotar, Prof Peter Colman, Dr Dana Westphal and colleagues, made the discovery.

Their research paper, entitled 'Bax Crystal Structures Reveal How BH3 Domains Activate Bax and Nucleate Its Oligomerization to Induce Apoptosis', was published in the journal Cell with an abstract at: http://www.cell.com/abstract/S0092-8674%2812%2901553-X.

Dr Czabotar said activation of the protein Bax was known to be an important event leading to apoptosis, but the method of activation had not been known.

"One of the key steps in cell death is that holes are punched into a membrane in the cell, the mitochondrial membrane," Dr Czabotar said.

"Once this happens the cell is going to go on and die," Dr Czabotar said.

"Bax is responsible for punching the holes in the mitochondrial membrane and visualizing its activation brings us a step closer to understanding the mechanics of cell death," Dr Czabotar said.

WEHI said that using the Australian Synchrotron, Dr Czabotar and colleagues were able to obtain detailed three-dimensional images of Bax changing shape as it moved from its inactive to active form, which ruptured mitochondrial membranes, removing the cell's energy supply and causing cell death.

"By using the powerful X-ray beams created by the synchrotron, we obtained structures of Bax that were really exciting," Dr Czabotar said.

"Bax is activated when small protein fragments called BH3-peptides bind to it," Dr Czabotar said.

"We saw that these peptides open up the Bax molecule like a key unlocking a padlock," Dr Czabotar said.

"This unlocked form of Bax can bind to another Bax molecule, which can then form larger Bax complexes that can go on to break up membranes in the cell," he said.

"As well as explaining the detail of how cell death occurs, our research could provide clues about how to design potential new therapeutic agents that target Bax," Dr Czabotar said.

"Now that we can see how Bax changes its shape to move from the inactive to the active form, it may be possible to block Bax activation, to prevent cell death in conditions such as neurodegenerative disorders, where illness is caused by excessive cell death," Dr Czabotar said.

"Similarly, agents that drive Bax into its active form could force immortal cells such as cancer cells to die, providing the basis for a potential new class of anti-cancer agents," Dr Czabotar said.

ALCHEMIA

Alchemia says it has recruited all 390 patients to its phase III trial of hyaluronic acid (HA)-irinotecan, on-time and on-budget.

Alchemia said the double-blind study was comparing the safety and efficacy of its Hyact technology in combination with standard chemotherapy drug irinotecan (HA-irinotecan) against irinotecan alone in second and third line metastatic colorectal cancer patients, as part of the folinic acid, fluorouracil and irinotecan (FOLFIRI) regimen.

Alchemia said that the primary endpoint would be reached when 350 patients had experienced disease progression and the initial expectations, was that would happen in the second half of 2013, but a statistical review and modeling on the available blinded data suggested that patients were continuing treatment for longer than expected.

The company said it was encouraged by the observation, but that meant that the primary endpoint was likely to be met early in 2014.

Alchemia said that the primary objective was to demonstrate that HA-irinotecan is superior, as indicated by an increase in progression-free survival of six weeks or more.

Alchemia executive chairman Dr Mel Bridges said the recruitment update was “an important milestone for the company - completed on time and within budget”.

“We are quite confident about funding this trial through to reporting the results next year,” Dr Bridges said. “The success of this trial will further validate the value shareholders can expect from the HA oncology assets.”

Alchemia said that the phase III protocol included an 80-patient sub-study being to investigate the pharmacokinetic and cardio-toxicity of HA-irinotecan, which had 53 patients enrolled and to improve recruitment, as well as increase the power of the overall study, it would open recruitment to a further 20 patients, bringing the total to 410 patients.

Alchemia said the additional patients did not affect the timing of the clinical trial endpoint where progression-free survival would be reported in the first half of 2014.

Alchemia was unchanged at 32 cents with 1.4 million shares traded.

BIONOMICS

Bionomics says that BNC375 for Alzheimers disease memory loss enhances episodic and working memory and its performance matches Donepezil in rats and mice

The research, entitled ‘BNC375, A Novel Positive Allosteric Modulator of the Alpha-7 Nicotinic Acetylcholine Receptor, Exhibits Cognitive Enhancement in Rodent Behavioural Models’ was to be presented today at the Australian Neuroscience Society meeting in Melbourne, at the Melbourne Convention Centre. The poster is available at: http://www.bionomics.com.au/siteFiles/files/news/Announcements_509.pdf.

Bionomics said that the poster highlighted data demonstrating the in-vivo memory enhancing properties of the drug candidate in rat and mouse models of cognitive impairment as well as data on the action of BNC375 on the receptor.

The company said that the data indicated that BNC375 enhanced both episodic memory and working memory and that it had equivalent performance compared to Donepezil, marketed by Pfizer as Aricept, with sales of $US2.5 billion sales in 2011.

Bionomics, chief executive officer Dr Deborah Rathjen said that BNC375 targeted Alzheimer’s disease and other conditions associated with significant memory loss.

“This latest drug candidate to come from our technology platform conforms to Bionomics’ focus on developing well differentiated drug candidates to treat serious conditions such as Alzheimer's disease, schizophrenia and Parkinson’s disease amongst others,” Dr Rathjen said.

Bionomics was up half a cent or 1.25 percent to 40.5 cents.

CALZADA

Calzada says recruitment for its 20 patient trial of Polynovo's Novosorb has been completed with results expected by May 2013.
Calzada said that the trial of the Novosorb negative pressure wound therapy dressing was supervised by the Royal Adelaide Hospital's Prof John Greenwood.
The company said that 15 patients completed their eight weeks of treatment, two were withdrawn for issues unrelated to the treatment and three were being treated.
Calzada said that 100 percent subsidiary Polynovo intended to file a 510(k) application for US Food and Drug Administration clearance of the Novosorb dressing to be marketed as a device, as safe and effective as an existing device.
The company said that the Novosorb dressing was tested in hard-to-heal pressure sores, also known as decubitus ulcers or bedsores and primarily due to the aging population, the incidence of difficult to treat pressure sores was growing, with an estimated 2.5 million US patients a year treated for pressure ulcers and the more advanced ulcers costing about $US70,000 a patient and the healthcare system about $US11 billion a year.
Calzada was up 0.3 cents or 6.7 percent to 4.8 cents.

CIRCADIAN TECHNOLOGIES

Circadian says that more than 30 patients in its phase I trial for advanced or metastatic solid tumors have received weekly VGX-100 at doses ranging from 1mg/kg to 20mg/kg.
Circadian said that the trial began in January, 2012 and completion of patient enrolment was expected by April 2013, with phase II studies expected to begin by the end of 2013.
The company said that principal investigator and UCLA Santa Monica professor of medicine Prof Lee Rosen presented a trial update at the International Symposium on Anti-Angiogenic Therapy in San Diego, California over the weekend.
Circadian said the presentation was entitled 'Phase I trial of VGX-100, an anti-VEGF-C monoclonal antibody, with or without Bevacizumab' and Prof Rosen discussed the rationale for VGX-100 in oncology, reviewed the trial design and provided an update.
The company said the primary objective of the study was to establish the safety profile of VGX-100, with secondary objectives including anti-tumor activity, biomarker levels and pharmacokinetics of VGX-100.
Circadian was up one cent or 3.4 percent to 30.5 cents.

PHARMAXIS

Montoya Investments and Graham Edwards have become substantial shareholders in Pharmaxis with the acquisition of 16,991,165 shares or 5.5 percent.
The initial substantial shareholder notice said that the Lower Hutt, New Zealand -based company primarily bought shares from February 2011 at prices ranging from 85.4 cents a share to $2.69 a share, with the single largest acquisition 4,000,000 shares at 73.9 cents a share on January 31, 2013, the day the US Food and Drug Administration Committee voted against approving Bronchitol for cystic fibrosis (BD: Jan 31, 2013).
Montoya said it sold 5,850,000 shares for $1.04 a share on December 23, 2011.
Pharmaxis fell half a cent or 0.7 percent to 71 cents with 1.6 million shares treated.